


EXHIBIT 13

 Mallinckrodt Pharmaceuticals	Title: HZQS- Identification, Investigation, and Reports of Controlled Substances Suspicious Orders	Effective Date: 08/17/15
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1. PURPOSE

This procedure outlines the Identification and Investigation of Suspicious Orders component of the Mallinckrodt Suspicious Order Monitoring ("SOM") Program and the reporting of any Suspicious Orders to DEA.

2. SCOPE

It is Mallinckrodt's corporate policy that orders for controlled substances which have been determined to be Suspicious Orders (significant deviation in order size, order frequency, or order pattern) will be reported to DEA upon discovery in accordance with 21 C.F.R. § 1301.74(b). Suspicious orders are held and will not be shipped, unless and until, Mallinckrodt's Controlled Substances Compliance Group completes its independent analysis of these suspicious orders and determines that the orders are not likely to be diverted into other than legitimate medical, scientific and industrial channels.

3. REFERENCES

- 3.1 21 C.F.R. § 1301.74(b)
- 3.2 Suspicious Order Report

4. DEFINITIONS

- 4.1 Suspicious Order: A direct order received by Mallinckrodt directly from a customer for a Schedule II - V Controlled Substance product which exceeds the internal limit set by the application of the three-tiered system of specifically created algorithms defined in this policy. Suspicious Orders will be reported to DEA upon discovery in accordance with 21 C.F.R. § 1301.74(b).
- 4.2 Tier 1: A monthly limit set annually for large volume wholesalers' or distributors' orders of Oxycodone 15 mg and 30mg SKUs. These products have been identified by DEA as particularly subject to diversion and abuse.
- 4.3 Tier 2: A standard algorithm with respect to volume which sets a monthly limit at: [REDACTED]
- 4.4 Tier 3: A monthly limit placed on a customer (based on customer Bill To address for a particular SKU for a particular amount.
- 4.5 SOM Team ("SOMT")
 - Associate General Counsel
 - Vice President Global Security or designee
 - Director of Government Reporting Compliance
 - Sr. Manager of Controlled Substances Compliance
 - Sr. Data Analyst (SOM Analyst)
 - Sr. Controlled Substances Compliance Coordinator

5. RESPONSIBILITIES

- 5.1 This policy is owned by the Sr. Manager, Controlled Substances Compliance ("MCSC") within the Legal Department and is applicable to the SOMT.
- 5.2 The SOM Analyst or designee will create and maintain Suspicious Order investigation files for all documentation related to such investigations. The files will be maintained in a location within the Legal Department.

6. PROCEDURE

- 6.1 Establishing and Reviewing Algorithms

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6.1.1 The SOMT is responsible for identifying which Tier applies to which controlled substances product orders and from which customers. These algorithms will be established by the SOMT based upon a detailed analysis of order history, quota statistics, IMS data, chargebacks and any other data deemed relevant by the SOMT. Algorithms will be subject to annual review by the SOMT and revised for the upcoming year, if necessary. The SOMT, at its discretion, may retain the services of a DEA consultant to assist in the establishment and review of the algorithms.

6.1.1.1 Algorithms or limits may be adjusted intra year by the SOMT due to changes in order history, quota statistics, IMS data, chargebacks, and other data deemed relevant by the SOMT.

6.1.1.2 The SOMT approval of algorithm adjustment will be documented.

6.2 Suspicious Order Reports

6.2.1 The algorithms will be programmed into the order system by Information Services as directed by the SOMT, to automatically prepare a twice daily Suspicious Order Report.

6.2.1.1 The Suspicious Order Report will be transmitted by e-mail to the DEA Field office Diversion Investigator responsible for the Mallinckrodt Hobart, NY facility

6.2.1.2 Each order in the Suspicious Order Report will be reviewed and investigated by the SOM Analyst or designee. All internal and external communications and the resolutions of all investigations shall be documented by the SOM Analyst or designee and placed in the Suspicious Order investigation files.

6.3 Ship-Hold and Cancellation

6.3.1 A ship-hold automatically will be placed on each order on the Suspicious Order Report until the final determination is made, in writing, with respect to the order by members of the SOMT.

6.3.1.1 No order in the Suspicious Order Report shall be released for shipment unless and until members of the SOMT determine that the order is not likely to be diverted from legitimate channels.

6.3.1.2 If it cannot be so determined, the order(s) will be cancelled and the fact of cancellation documented.

6.4 Investigation of Tier 1, Tier 2 or Tier 3 Suspicious Orders

6.4.1 The SOM Analyst or designee will prepare a written report of the Suspicious Orders upon discovery and document the reporting of the Suspicious Orders to DEA. The files will be maintained in a location within the Legal Department.

6.4.2 The SOM Analyst or designee, at his/her discretion, may review orders of that product from other customers in the same industry segment as the ordering customer.

6.4.3 The SOM Analyst or designee will conduct the first level of investigation by obtaining more detailed reports concerning the Suspicious Order from the order system and further analyzing the Suspicious Order within the context of that information.

6.4.4 The SOM Analyst or designee, at his/her discretion, may confer (but is not required to confer) with the Commercial Group representative (Product Manager for the product in the Suspicious Order and/or the National Account Manager) responsible for the customer placing the order to obtain additional information concerning the Suspicious Order.

6.4.5 After completion of the initial investigation of the Suspicious Order, the SOM Analyst or designee will forward notification that the Suspicious Order report is ready for review to the DGRC or MCSC.

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- 6.4.6 The DGRC or MCSC will review the report, document the recommended disposition of the order within the report and respond that the order shall be released, request additional investigation, or if the order is to be cancelled.
- 6.4.7 If additional investigation is required, the SOM Analyst or designee may confer (but is not required to confer) with his/her SOM counterpart at the customer who placed the order to obtain additional information and a detailed explanation concerning the unusual size, pattern, or frequency of the order. The SOM Analyst will document the information and, if necessary, confer with the Commercial Group to confirm the plausibility of the explanation.
- 6.4.8 The SOM Analyst or designee will then present the results of his/her investigation directly to DGRC or MCSC and Sr. Controlled Substances Compliance Coordinator and make a recommendation to release the order for shipment, request additional investigation, or cancel the order.
- 6.4.9 The SOM Analyst or designee will release the order for shipment, request additional investigation, or cancel the order.
- 6.4.10 If the recommendation to cancel the order is accepted by the DGRC or MCSC and Sr. Controlled Substances Compliance Coordinator,
- 6.4.10.1 Customer Service will cancel the order as directed by the SOM Analyst or designee
- 6.4.10.2 The SOM Analyst will notify the VP of Commercial Operations, the Product Manager for the product in the Suspicious Order and the National Account Manager responsible for the customer placing the order of the decision to reject and cancel the order.
- 6.4.10.3 The SOM Analyst, at his/her discretion, may notify his/her SOM counterpart at the customer of the SOMT's decision to reject and cancel the order.

7. ATTACHMENTS

7.1 NONE

8. RELATED FORMS

8.1 NONE

9. REVISION HISTORY

Revision Number	Effective Date	Section	Revision
4	08/17/2015		Changed "Covidien" references to "Mallinckrodt"
			Personnel titles updated throughout procedure
		2.0	Verbiage modified to reflect consistency between related SOPs.
		3.1	Deleted "HZQS-DMS" reference
		4.5	Changed SOM Leadership Team to SOM Team
		5.1	Streamlined.
		6.4	Updated responsible party in applicable areas.

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3	03/07/13	4 6.5	Added Tier 3 information Deleted redundant section
2	11/01/12	4.3	The multiplier within the standard algorithm with respect to volume changed from [REDACTED] [REDACTED] [REDACTED]
1	10/18/12	6.4.9 and 6.5.9 All	If the SOM Leadership Team determines the explanation for the Suspicious Order is not sufficient, the SOM Leadership Team will: (1) reject the Suspicious Order and (2) direct Customer Service Representative to cancel the Suspicious Order. Customer Service will cancel the Suspicious Order as directed by the SOM Leadership Team The MCSC will notify the VP of Commercial Operations, the Product Manager for the product in the Suspicious Order and the National Account Manager responsible for the customer placing the order of the decision to reject the order The MCSC, at his/her discretion, May notify his/her SOM counterpart at the customer of the SOM Leadership Team's decision to reject the order All references to Unusual Order Report (UOR) changed to Suspicious Order Report (SOR)
NEW	09/20/12		New document.